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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/654,546	09/03/2003	Timothy J. Guzi	OC01617K	3990

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
MCKENZIE, THOMAS C	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 01/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/654,546	Applicant(s) GUZI ET AL.	
	Examiner Thomas McKenzie, Ph.D.	Art Unit 1624	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 December 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

6. ☒ Newly proposed or amended claim(s) *3,10-13 and 27-30* would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *27-30*.
   Claim(s) objected to: *3 and 10-13*.
   Claim(s) rejected: *1,2,4-9,14-26,31-34 and 36-47*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.

12. ☒ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). 12/15/03 & 7/16/04

13. ☐ Other: _____.

Thomas C. McKenzie, Ph.D.
Primary Examiner
Art Unit: 1624

Continuation of 5. Applicant's reply has overcome the following rejection(s): Applicants' deletion of the offending proviso from claim 1 overcomes the new matter rejection made in point #7 of the Final rejection. Applicants' deletion of (CHR5)aryl as a possible value for radical R overcomes both the anticipation and obviousness rejection over Hirai (JP 61-57587 A2) made in points #8 and #9 of the Final Rejection. This amendment also overcomes the anticipation rejections over Hirai (JP 61-57587 A2) and Ruhter ('137) made in points #9 and #10 respectively in the non-Final Rejection of 6/22/05. Applicants' deletion of alkyl as a possible value for variable R3 overcomes the anticipation rejection over O'Brien (GB 1,412,017) made in point #8 of the non-Final rejection. Applicants' deletion of the offending species from the present claims overcomes the provisional double patenting rejection made in point #10 of the Final Rejection.

Continuation of 11. does NOT place the application in condition for allowance because: This action is in response to amendments filed on 12/15/05. Applicant has amended claims 1-3, 5, 19, 20, 27-34, 37, 40, 43, and 45. Applicant has canceled claim 35. Claims 1-47 were previously rejected. There are forty-six claims pending and forty-six under consideration. Claims 1-30 and 42 are compound claims. Claims 40 and 41 are composition claims. Claims 31-35, 36-39, and 43-47 are method of using claims. This is the third action on the merits. The application concerns some N-benzyl and N-(pyridinylmethyl)-pyrazolo[1,5-a]pyrimidin-7-amine compounds, compositions, and uses thereof.

Claims 1, 2, 4-9, 14-26, 31-34 and 36-47 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the definitions of the variables R and R2, the phrase "heterocyclylalkyl" is indefinite. The phrase is not defined in the specification and while the individual parts of the compound word, "hetero", "alkyl", and "cyclo" do have meaning, the triple combination is ambiguous.

Applicants make the statement that an alkyl group substituted by a heterocyclyl, like piperidine-methyl is intended and point to seven examples in the specification as examples of what they intend. While this clarification is laudable, there is nothing in the claims or specification making this definition. Why are Applicants now selecting this meaning from the three possible meaning first suggested by the Examiner? The claims measure the invention. The U.S. Court of Customs and Patent Appeals wrote In re Priest, 199 USPQ 11 "We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim." In re Prater, 56 CCPA 1381, 1396, 415 F.2d 1393, 1405, 162 USPQ 541, 551 (1969)." the claims measure the invention. The U.S. Court of Customs and Patent Appeals wrote In re Priest, 199 USPQ 11 "We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim." In re Prater, 56 CCPA 1381, 1396, 415 F.2d 1393, 1405, 162 USPQ 541, 551 (1969)."

Claims 31-34 and 37-39 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The specification does not set forth any steps involved in determining how to identify what diseases and treatments applicant is intending to encompass.

Applicants make the argument that their proposed amendments will overcome this rejection. However, the claims are clearly directed to disease treatment. Claim 33 uses the word diseases and claim 34 uses the word treatment. Only patients have compounds administered to them as required by claim 32. However, Applicants' will not, or cannot, tell us what diseases are to be treated. Without such information a potential infringer would have no clue as to the metes and bounds of the claims.

Claims 31-34, 36-41, and 43-47 remain rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for treating any human disease. The specification does not enable any physician skilled in the art of medicine, to make the invention commensurate in scope with claims 31-34, 36-39, and 43-47 or to use claims 40 and 41. The how to make requirement of the enablement statute, when applied to process claims, refers to operability and how to make the claimed process work. The skilled physician would not know how to use composition claims 40 and 41, containing compounds of no known medical use.

Claims 31-34, 36-41, and 43-47 remain rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for treating any human disease. The specification does not enable any physician skilled in the art of medicine, to make the invention commensurate in scope with claims 31-34, 36-39, and 43-47 or to use claims 40 and 41. The how to make requirement of the enablement statute, when applied to process claims, refers to operability and how to make the claimed process work. The skilled physician would not know how to use composition claims 40 and 41, containing compounds of no known medical use.

Applicants make the argument that their Rule 132 declaration provides the enablement for disease treatment. The declaration was not timely filed and the declaration fails to establish any nexus between the ability of compounds to inhibit the CDK1 enzyme and clinical efficacy for the treatment of any disease.